

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were completed in January 2015.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-418

Trade Name: BetaVet®
Ingredients: Betamethasone sodium phosphate and betamethasone acetate
Sponsor: Luitpold Pharmaceuticals, Inc.
Approval Date: January 11, 2015
Status: Rx
Route: Intra-articular injection
Species: Horses
Drug Form: Injectable suspension
Concentration: 6 mg/mL as 3.15 mg betamethasone sodium phosphate and 2.85 mg betamethasone acetate
Indications: For the control of pain and inflammation associated with osteoarthritis in horses.
Exclusivity: 3 years

NADA Number: 141-435

Trade Name: advantus™
Ingredients: Imidacloprid
Sponsor: Piedmont Animal Health
Approval Date: January 9, 2015
Status: OTC
Route: Oral
Species: Dogs
Drug Form: Chewable tablet
Concentration: Each chewable tablet contains either 7.5 mg or 37.5 mg of imidacloprid
Indications: advantus™ kills adult fleas and is indicated for the treatment of flea infestations on dogs and puppies 10 weeks of age and older and weighing 4 pounds or greater.
Exclusivity: 3 years

ANADA Number: 200-527

Trade Name: Enrofloxacin Antibacterial Injectable Solution
Pioneer: Baytril® Antibacterial Injectable Solution
Ingredients: Enrofloxacin
Sponsor: Putney, Inc.
Approval Date: January 9, 2015
Status: RX
Route: Intramuscular injection
Species: Dogs
Drug Form: Injectable solution
Concentration: 22.7 mg/mL enrofloxacin
Indications: For the management of diseases in dogs associated with bacteria susceptible to enrofloxacin.

ANADA Number: 200-576

Trade Name: Gentamicin Sulfate Ophthalmic Solution
Pioneer: Gentocin® Ophthalmic Solution
Ingredients: Gentamicin sulfate
Sponsor: Akorn Animal Health, Inc.
Approval Date: January 30, 2015
Status: RX
Route: Ophthalmic

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Species: Dogs and cats
Drug Form: Ophthalmic Solution
Concentration: Gentamicin sulfate equivalent to 3.0 mg gentamicin per mL of solution
Indications: For the topical treatment of conjunctivitis caused by susceptible bacteria in dogs and cats.

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-280

Trade Name: Zilmax® plus Rumensin® plus Tylan® plus MGA®
Ingredients: Zilpaterol hydrochloride 4.8 %; monensin, USP; tylosin phosphate; and melengestrol acetate
Sponsor: Intervet, Inc.
Approval Date: January 14, 2015

This supplement provides for: 1) component feeding of 60 mg zilpaterol hydrochloride/head/day in combination with feed containing monensin, USP; tylosin phosphate; and melengestrol acetate for increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*, and suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 20 to 40 days on feed, and 2) adding the following statement to the labeling for the use of zilpaterol hydrochloride in complete feed when fed in combination with monensin, USP; tylosin phosphate; and melengestrol acetate: "CAUTION: Not to be fed to cattle in excess of 90 mg/head/day in complete feed. If pen consumption of complete feed exceeds 26.5 lb/head/day (90 percent dry matter basis), zilpaterol should not be fed in complete feed."

Sponsor Change

NADA Numbers: 048-480, 065-256

Previous Sponsor: ADM Alliance Nutrition, Inc.
New Sponsor: Pharmgate LLC

ANADA Number: 200-323

Previous Sponsor: Hikma Pharmaceuticals LLC
New Sponsor: Hikma International Pharmaceuticals LLC (Exempt Company)

Sponsor Name Change

Previous Name: Merial Ltd.
New Name: Merial, Inc.

Sponsor Address Change

Sponsor: Intervet, Inc.
New Address: 2 Giralda Farms
Madison, NJ 07940

Patent Additions

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The following corrections or additions to the list were completed in January 2015.

NADA Number: 141-339

Patent number: 8,937,044

Expiration Date: September 30, 2024